Legend: (New Rules)
Regular Print = Proposed new language
House Bill 2131 of the 84th Texas Legislature (Regular Session)

§ 133.201 Background and Purpose.

The purpose of this section is to implement Health and Safety Code, Chapter 32, Subchapter D, Centers of Excellence for Fetal Diagnosis and Therapy designation, to achieve healthy fetal outcomes in this state.

§ 133.202 Definitions.

The following words and terms, when used in this subchapter, shall have the following meanings, unless the context clearly indicates otherwise.

(1) Antenatal--occurring or existing before birth, referring to both the care of the woman during pregnancy and the growth and development of the fetus.

(2) Available--relating to staff who can be contacted for consultation at all times without delay.

(3) Center--a facility designated as a Center of Excellence for Fetal Diagnosis and Therapy.

(4) Commission--The Health and Human Services Commission.

(5) Department--The Department of State Health Services.

(6) Designation--A formal recognition by the department of a facility's fetal diagnosis and therapy care capabilities and commitment, for a period of three years.

(7) Feta--of, relating to, or being a fetus.

(8) FCMD—Fetal Center Medical Director

(9) FCPM—Fetal Center Program Manager

(10) Executive Commissioner--The Executive Commissioner of the Health and Human Services Commission.

(11) Innovation--a new method of investigation or an experiment undertaken to benefit an individual patient.

(12) Level I evidence-based metrics-- Evidence from a systematic review of all relevant randomized controlled trials (RCTs) or evidence-based clinical practice guidelines based on systematic reviews of RCTs, or of best available consensus of the major national perinatal organizations.

(13) Maternal--Pertaining to the mother.

(14) Maternal-Fetal Patient--pertaining to the pregnant mother and her fetus(es).

(15) Office--Office of Emergency Medical Services (EMS)/Trauma Systems Coordination.

(16) Onsite—at the facility and able to rapidly arrive at the patient bedside for urgent requests.

(17) PCR--Perinatal Care Region.

(18) Perinatal--Of, relating to, or being the period around childbirth, especially the five months before and one month after birth.

(19) Research--an investigation or experiment undertaken to create generalized knowledge about a particular subject.

§ 133.203 General Requirements.

(a) The Office of Emergency Medical Services (EMS)/Trauma Systems Coordination (office) shall recommend to the Executive Commissioner of the Health and Human Services Commission (executive commissioner) the designation of an applicant/healthcare facility as a Center of Excellence for Fetal Diagnosis and Therapy for each location of a facility, which the office deems appropriate.

(b) A healthcare facility is defined under this subchapter as a single location where inpatients receive hospital services or each location if there are multiple buildings where inpatients receive hospital services and are covered under a single hospital license.

(c) Each location shall be considered separately for designation and the office will determine the designation for that location, based on, but not limited to, the location's own resources and level of care capabilities;

Perinatal Care Region (PCR) capabilities; and compliance with Chapter 133, concerning Hospital Licensing.

(d) A designated Center of Excellence for Fetal Diagnosis and Therapy shall:

(1) provide the highest level of maternal, fetal, and neonatal care for patients with the least to most complex fetal conditions;

(2) provide at a minimum, all fetal therapies and interventions proven effective antenatally based on level I evidence-based metrics;

(3) have skilled medical staff and personnel with documented training, competencies and continuing education specific for the patient population served;

(4) offer fetal diagnosis and therapy through an extensive multi-specialty clinical program that is affiliated and collaborates extensively with a medical school in this state;

(5) demonstrate a significant commitment to research in and advancing the field of fetal diagnosis and therapy;

(6) offer advanced training programs in fetal diagnosis and therapy;

(7) provide appropriate long-term monitoring and follow-up care for patients, including measuring short-term and long-term patient diagnostic and therapeutic outcomes;

(8) provide outreach and education to maternal and/or neonatal designated facilities;

(9) hold current verification for maternal-fetal surgical care from an organization approved by the Department of State Health;

(10) hold current verification from the American College of Surgeons (ACS) as a Level I Children's Surgery Center;

(11) be designated by the Department of State Health Services as a Level IV Maternal Level of Care facility;

(12) be designated by the Department of State Health Services as a Level IV Neonatal Level of Care facility;

(13) meet twice a year as determined by the department, with other designated Centers of Excellence for Fetal Diagnosis and Therapy (CEFDT):

(A) for the purposes of mutual collaboration; and

(B) to discuss inclusion criteria for fetal intervention and biopsychosocial outcome variables both short-term and long-term;

(14) participate in a multi-disciplinary performance improvement committee with other designated CEFDT; and

(15) have facility specific treatment outcomes vetted and approved by the department for public posting on the facility website for public access and/or redirect the public to the facility specific outcomes posted on the department's website.

(e) Facilities seeking Centers of Excellence for Fetal Diagnosis and Therapy designation shall be surveyed through an organization approved by the office to verify that the facility is meeting office-approved relevant requirements. The facility shall bear the cost of the survey.

§ 133.204 Designation Process

(a) Designation application packet. The applicant shall submit the packet, inclusive of the following documents to the Office of EMS/Trauma Systems Coordination (office) within 120 days of the facility's verification for maternal-fetal surgical care:

(1) an accurate and complete designation application form for designation; including full payment of the designation fee as listed in subsection (d) of this section;

(2) evidence of current verification for maternal-fetal surgical care, including patient care reviews;

(3) evidence of current verification from the American College of Surgeons as a Level I Children's Surgery Center; including patient case reviews;

(4) a letter of support from the facility's governing board supporting provisions for the collection and evaluation of short and long-term outcomes;

(5) evidence of participation in the CEFDT meetings twice a year and multi-disciplinary performance improvement committee meetings;

(6) evidence of outcomes posted for public access; and

(7) any subsequent documents requested by the office.

(b) Renewal of designation. The applicant shall submit the documents described in subsection (a)(1) - (7) of this section to the office not more than 180 days prior to the designation expiration date and at least 60 days prior to the designation expiration date.

(c) If a facility seeking designation fails to meet the requirements in subsection (a)(1) - (7) of this section, the application shall be denied.

(d) Non-refundable application fee of $2,500.00 for the three year designation period shall be submitted with the application or renewal.

(e) If a facility disagrees with the designation determination by the office for initial designation or renewal of designation, it may make an appeal in writing not later than 60 days after issuance of the determination to the director of the office. The written appeal must include a signed letter from the facility's governing board with an explanation of the basis for its appeal.

(1) If the office upholds its original determination, the director of the office will give written notice of such to the facility not later than 30 days of its receipt of the applicant's complete written appeal.

(2) The facility may, not later than 30 days of the office's issuance of written notification of its denial, submit a written request for further review. Such written appeal shall be submitted to the Associate Commissioner of the Division for Consumer Protection (associate commissioner).

(f) The survey organization shall provide the facility with a written, signed survey report regarding their evaluation of the facility's compliance with the Centers of Excellence for Fetal Diagnosis and Therapy program requirements. This survey report shall be forwarded to the facility no later than 30 days of the completion date of the survey. The facility is

responsible for forwarding a copy of this report to the office if it intends to continue the designation process.

(g) The office shall review the application packet documents submitted by the facility, to determine compliance with the centers of excellence for fetal diagnosis and therapy program requirements.

(1) A recommendation for designation shall be made to the commissioner based on compliance with the requirements.

(2) A centers of excellence for fetal diagnosis and therapy designation shall not be denied to a facility that meets the minimum requirements for designation.

(A) If a facility disagrees with the office's decision regarding its designation application or status, it may request a secondary review by a designation review committee.

(B) Membership on a designation review committee will:

(i) be voluntary;

(ii) be appointed by the office director;

(iii) be representative of fetal diagnosis and therapy providers and the highest levels of neonatal and maternal care designated facilities; and

(iv) include representation from the office.

(C) If a designation review committee disagrees with the office's recommendation, the records shall be referred to the associate commissioner for recommendation to the commissioner.

(D) If a facility disagrees with the office's recommendation at the end of the secondary review, the facility has a right to a hearing, in accordance with a hearing request referenced in §133.121(9) of this title (relating to Enforcement Action), and Government Code, Chapter 2001.

§ 133.205 Program Requirements.

(a) A designated Center of Excellence for Fetal Diagnosis and Therapy (center) shall provide patient-centered and family-centered health care. The center's environment for maternal-fetal care shall comprehensively meet the physiologic and psychosocial needs of the pregnant women, their infants, and families.

(b) Program Plan. The center shall develop a written plan of an organized program that includes a detailed description of the scope of services available to the maternal-fetal patient, define the maternal-fetal patient population evaluated and/or treated by the center, which is consistent with accepted professional standards of practice for maternal-fetal care, and ensures the health and safety of patients.

(1) The written plan and the program policies and procedures shall be reviewed and approved by the center's governing body. The governing body shall ensure that the requirements of this section are implemented and enforced.

(2) The written Fetal Center program plan shall include, at a minimum:

(A) program policies and procedures that are:

(i) based upon current standards of fetal diagnosis and therapy practice; and

(ii) adopted, implemented and enforced for the maternal-fetal services it provides;

(B) a periodic review and revision schedule for all maternal-fetal care policies and procedures;

(C) a Quality Assessment/Performance Improvement (QAPI) Program as described in §133.41(r) of this title (relating to Hospital Functions and Services). The facility shall demonstrate that the Fetal Center program evaluates the provision of maternal-fetal care on an ongoing basis, identify opportunities for improvement, develop and implement improvement plans, and evaluate the implementation until a resolution is achieved. The Fetal Center program shall measure, analyze, and track quality indicators or other aspects of performance that the center adopts or develops that reflect processes of care and is outcome based. Aggregate patient data must be continuously

reviewed for trends. QAPI data must be submitted to the department as requested;

(D) requirements for minimal credentials for all staff participating in the care of maternal-fetal patients;

(E) provisions for providing continuing staff education; including annual competency and skills assessment that is appropriate for the patient population served; and

(F) procedures to ensure the availability of all necessary equipment and services to provide the appropriate level of care and support of the patient population served.

(c) Medical Staff. The facility shall have an organized, effective fetal therapy and diagnosis program that is recognized by the medical staff and approved by the center's governing body. The credentialing of the medical staff shall include a process for the delineation of privileges for maternal-fetal care.

(d) Medical Director. There shall be an identified Fetal Center Medical Director (FCMD) responsible for the provision of fetal therapy and diagnosis services and credentialed by the facility for the treatment of maternal-fetal patients.

(1) The FCMD shall be a physician who:

(A) is a board certified maternal fetal medicine (MFM) physician or a board certified pediatric surgeon, both with additional training and expertise in maternal-fetal care and fetal interventions;

(B) demonstrates administrative skills and oversight of the Fetal Center QAPI Program;

(C) completes annual continuing medical education specific to fetal medicine and/or fetal interventions;

(D) frequently and actively participates in maternal-fetal care and fetal interventions at the facility where medical director services are provided; and

(E) maintains active staff fetal privileges as defined in the facility's medical staff bylaws.

(2) The Fetal Center Medical Director shall have the authority and responsibility to monitor maternal-fetal patient care from outpatient navigation, admission, stabilization, operative intervention(s) if applicable, through discharge, inclusive of the QAPI Program.

(3) The responsibilities and authority of the FCMD shall include but are not limited to:

(A) examining qualifications of medical staff requesting fetal diagnosis and therapy privileges and making recommendations to the appropriate committee for such privileges;

(B) collaborating with the FCPM in areas to include but not limited to: developing and/or revising policies, procedures and guidelines for maternal-fetal care, assuring medical staff and personnel competency, education and training in maternal-fetal care; and directing the QAPI Program that is specific to maternal-fetal care and fetal interventions, is ongoing, data driven and outcome based.

(C) Frequently leading and participating in the Fetal Center QAPI meetings;

(D) Participating in the CEFDT meetings and the CEFDT multi-disciplinary performance improvement committee; and

(E) providing an annual report of aggregate short-term and long-term outcomes data as requested by the department.

(e) Fetal Center Program Manager (FCPM). There shall be an identified Fetal Center Program Manager (FCPM) responsible for the provision of fetal diagnosis and therapy clinical care services for maternal-fetal patient.

(1) The FCPM shall be a registered nurse who:

(A) has experience and/or training in maternal-fetal care and fetal interventions;

(B) demonstrates administrative skills and oversight of the Fetal Center QAPI Program;

(C) completes annual continuing education specific to maternal-fetal care and fetal interventions; and

(D) frequently and actively participates in maternal-fetal care at the facility where program manager services are provided.

(2) The Fetal Center Program Manager shall have the authority and responsibility to monitor maternal-fetal patient care from outpatient navigation, admission, stabilization, operative intervention(s) if applicable, through discharge, inclusive of the QAPI Program.

(3) The responsibilities and authority of the FCPM shall include but are not limited to:

(A) examining qualifications of staff providing maternal-fetal care services;

(B) collaborating with the FCMD in areas to include but not limited to: developing and/or revising policies, procedures and guidelines for maternal-fetal care, assuring medical staff and personnel competency, education and training in maternal-fetal care; and directing the QAPI Program that is specific to maternal-fetal care and fetal interventions, is ongoing, data driven and outcome based;

(C) Frequently leading and participating in the Fetal Center QAPI meetings;

(D) Participating in the CEFDT meetings and the CEFDT multi-disciplinary performance improvement committee; and

(E) providing an annual report of aggregate short-term and long-term outcomes data as requested by the department.

(f) The facility shall identify medical staff responsible for the provision of maternal-fetal care services, available for face-to-face consultation, and credentialed by the facility for the treatment of maternal-fetal patients, to include:

(1) a board-certified/eligible Maternal Fetal Medicine (MFM) physician, who shall:

(A) have primary responsibility for the direct, comprehensive, and coordinated medical care of patients undergoing fetal interventions; and

(B) be available at all times to the bedside within a time period consistent with current standards of professional practice and maternal-fetal care.

(2) a board-certified pediatric surgeon with training and expertise in fetal intervention;

(3) a board certified pediatric neurosurgeon with training and expertise in fetal intervention;

(4) a board certified neonatologist with training and expertise in the care of neonates following fetal interventions;

(5) A board certified pediatric cardiologist with expertise in the performance and interpretation of fetal echocardiography shall be available and provide interpretation, within 2 hours of an urgent request and within 24 hours for other requests, upon completion of the study;

(6) A board certified anesthesiologist with expertise in maternal-fetal physiology and uterine relaxation methods shall be available for consultation and available at all times if anesthesia is required for fetal interventions;

(7) a board certified pediatric urologist;

(8) a board certified pediatric nephrologist;

(9) a board certified pediatric Palliative Care Medicine physician; and

(10) Other board certified pediatric subspecialists including but not limited to: cardiovascular surgery, craniofacial surgery, gastroenterology, orthopedic surgery, plastic surgery and rehabilitative medicine.

(11) The identified medical staff responsible for the provision of maternal-fetal care services shall:

(A) complete annual continuing medical education specific to maternal-fetal care and fetal interventions;

(B) have frequent and active participation in maternal-fetal care and fetal interventions at the fetal center; and

(C) maintain active staff fetal diagnosis and therapy privileges as defined in the facility's medical staff bylaws.

(g) Medical Ethicist. A medical ethicist with expertise in clinical perinatal medical ethics shall be an active member of the fetal diagnosis and therapy program, including but not limited to: frequent participation in fetal center conferences, providing ethical consultations and participation in research.

(h) Genetic Counseling. Board eligible/certified genetic counselor(s) or a board eligible/certified physician with specialized training in prenatal genetic counseling shall be available for onsite face-to-face prenatal consultation as requested.

(i) Palliative Care. Personnel with training and/or experience in palliative care shall be available onsite at all times for prenatal and postnatal counseling of families.

(1) Personnel shall have perinatal-specific training in the support of maternal and/or pediatric patients and families.

(2) Personnel shall be trained to organize clinical protocols and birth plans, and to provide staff education.

(j) Child Life Specialist. A child life specialist shall be available for onsite consultation as requested and be licensed as a Certified Child Life Specialist (CCLS).

(k) Clinical Coordinator(s) shall be identified and the primary point of contact for the family.

(1) At least one Clinical Coordinator shall be a registered nurse with experience in maternal or neonatal care; and

(2) Clinical Coordinators engaged in research shall have completed the research ethics training/human subjects' protection training as appropriate.

(l) Medical Imaging Services.

(1) A board certified pediatric radiologist with expertise in the interpretation of fetal MRI shall be available and provide interpretation within 24 hours upon completion of study;

(2) Perinatal Sonographer.

(A) Shall be registered through the American Registry for Diagnostic Medical Sonography, Cardiovascular Credentialing International, American Registry for Radiologic Technologists, or an office approved equivalent.

(B) Shall have documented continuing education as required for advanced certifications, and demonstrate competence in mainstream fetal diagnostic ultrasounds, and new diagnostic modalities as available.

(3) Ultrasound imaging. The ultrasound unit shall be accredited by The American Institute of Ultrasound in Medicine or the American College of Radiology or an organization approved by the department.

(4) Fetal Echocardiography. The facility's Fetal Echocardiography program shall be accredited by The American Institute of Ultrasound in Medicine or the Intersocietal Accreditation Commission (IAC) or an organization approved by the department.

(5) Magnetic Resonance Imaging (MRI). The facility's MRI program shall be accredited by The American College of Radiology or an organization approved by the department.

(m) Laboratory Services.

(1) Perinatal pathology services shall be available onsite.

(2) Reference lab capabilities, or agreements with specialized testing centers, shall be available for specialized testing for perinatal genetic testing, fetal conditions, and infections.

(n) Fetal Center Innovation Committee. A multidisciplinary, objective committee will review fetal interventions that are innovative, but not mainstream medicine or research. The committee shall include medical personnel with maternal-fetal knowledge and expertise, ethicists, genetic counselors, and non-medical patient advocates, as appropriate for the

proposed study. The chair of the committee shall have an independent objective view of the proposed intervention. The members of the committee may or may not be directly involved with the Fetal Center, but shall not be directly involved in the proposed innovation. The committee decisions shall be independent and without conflict of interest, either due to direct care of the patient or by affiliation or financial gain. Documentation of in-depth discussions and actions taken will be maintained by the center. All non-standard fetal interventions shall have formal approval by the committee prior to the intervention. The committee has the final authority to approve or disapprove the innovative intervention.

(o) The Fetal Center shall provide a monthly multidisciplinary conference, involving fetal center medical staff, nurses, ethicist(s), and ancillary staff, to discuss the options for prenatal and postnatal management of fetal anomalies and other conditions. Fetal intervention(s) performed emergently prior to the conference will be discussed at the next monthly meeting after the procedure. The Facility shall make and keep documentation of meetings, in depth discussion of the options, and plan for management for all fetal therapy patients.

§ 133.206 Surveyor(s).

(a) A Center of Excellence for Fetal Diagnosis and Therapy shall be surveyed by a board certified pediatric surgeon with training and expertise in fetal interventions, all approved in advance by the office and currently active in the management of maternal-fetal patients at a fetal center providing the same level of maternal-fetal care.

(b) Office-credentialed surveyors must meet the following criteria:

(1) have at least three years of experience in the care of maternal-fetal patients;

(2) be currently employed/practicing in the coordination of care for maternal-fetal patients;

(3) have direct experience in the preparation for and successful completion of a Centers of Excellence for Fetal Diagnosis and Therapy verification/designation;

(4) have successfully completed an office-approved Centers of Excellence for Neonatal Diagnosis and Therapy site surveyor course and be successfully re-credentialed every four years; and

(5) be a pediatric surgeon who is board certified, has demonstrated expertise in fetal interventions, and has successfully completed an office approved site survey internship.

(c) All surveyor(s), shall come from a Perinatal Care Region outside the center's location and at least 100 miles from the center. There shall be no business or patient care relationship or any potential conflict of interest between the surveyor or the surveyor's place of employment and the center being surveyed.

(d) The survey(s) shall evaluate the center's compliance with the designation criteria by:

(1) reviewing medical records; staff rosters and schedules; documentation of QAPI Program activities including peer review; the program plan; policies and procedures; and other documents relevant to fetal diagnosis and therapy services;

(2) reviewing equipment and the physical plant; and

(3) conducting interviews with facility personnel; surveyors may meet privately with individuals or groups of personnel.